United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

MINERVA SURGICAL, INC.,

Plaintiff,

v.

HOLOGIC, INC., et al.,

Defendants.

Case No. 3:17-cv-02013-JD

ORDER RE PRELIMINARY INJUNCTION

Re: Dkt. No. 35

Plaintiff Minerva Surgical, Inc. ("Minerva") and defendant Hologic, Inc. ("Hologic") are competing suppliers of endometrial ablation devices. Dkt. No. 34-4 at 1. These devices treat abnormally heavy menstrual bleeding by destroying the uterine lining. Dkt. No. 51-4 at 1-2. In February 2017, Hologic began U.S. distribution of a new device called the NovaSure ADVANCED ("ADVANCED"). *Id.* In April 2017, Minerva filed this suit to allege that ADVANCED infringes one of its patents, U.S. Patent No. 9,186,208 ("the '208 patent"). Dkt. No. 1. In August 2017, Minerva moved for a preliminary injunction enjoining sales of ADVANCED. Dkt. No. 34-4.

Both parties' devices are designed to insert an expandable and contractible frame into the patient's uterus through the cervical canal. *See, e.g.*, *id.* at 3-4. The frame consists of "inner" and "outer" elements (also called flexures or struts in the parties' papers) that expand to bring a membrane into contact with the uterine cavity. Once in place, the membrane is used to apply energy sufficient to destroy the uterine lining. The Minerva Endometrial Ablation System ("Minerva EAS") generates heat by ionizing argon gas, Dkt. No. 35-5 at 3, while ADVANCED and its predecessor, the NovaSure CLASSIC ("CLASSIC"), use radio-frequency energy. Dkt. No. 35-6 at 2.

The parties agree that Minerva's infringement case turns on Claim 13 of the '208 patent. Claim 13 describes, in relevant part, a system for endometrial ablation with a frame "wherein the inner and outer elements have substantially dissimilar material properties ['SDMP']." Dkt. No. 35-3 at 22:43-45. The main question for the injunction motion is whether ADVANCED infringes Claim 13.

LEGAL STANDARD

Injunctive relief is "an extraordinary remedy never awarded as of right." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131 (9th Cir. 2011) (quoting *Winter*, 555 U.S. at 20).

In patent cases, an injunction should not be granted when the defendant "raises a substantial question concerning either infringement or validity." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). If the Court, after considering the evidence, is persuaded that a substantial question exists, "the patentee by definition has not been able to show a likelihood of success at trial on the merits." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1379-80 (Fed. Cir. 2009).

Irreparable harm will not be presumed even if the moving party demonstrates likely infringement and validity. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006); *Flexible Lifeline Sys., Inc. v. Precision Lift, Inc.*, 654 F.3d 989, 995-96 (9th Cir. 2011). As part of the irreparable harm showing, the moving party must demonstrate a causal nexus between infringement and harm, because "[s]ales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons other than the patented feature." *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012). "If all but an insignificant number of purchases from the infringer would have been made even without the infringing feature, the causal connection to the asserted lost-sale-based injury is missing." *Genband US LLC v. Metaswitch Networks Corp.*, 861 F.3d 1378, 1384 (Fed. Cir. 2017).

DISCUSSION

I. Likelihood Of Success On The Merits

As an initial matter, Minerva has complicated this key inquiry by trying to change its construction of Claim 13 late in the process. Minerva originally construed SDMP to mean that "the inner and outer frame elements have different thickness or width and different composition or treatment." Dkt. No. 34-4 at 8. Minerva touted this as "the most natural reading of the term as used in the '208 patent." *Id*. Hologic accepted Minerva's construction for purposes of the preliminary injunction motion. Dkt. No. 51-4 at 5. Under this construction, the parties agreed that the elements should satisfy both requirements: they should have different thickness or width, and they should also have different composition or treatment. *Id.*; Dkt. No. 66-4 at 3. The parties also agreed that ADVANCED's inner and outer elements have different thickness or width and the same composition. *Id.* As a result, Minerva's infringement claim would turn on whether ADVANCED's inner and outer elements underwent different treatments.

These agreed-upon constructions were the foundation for this motion. Hologic properly banked on them to argue in its opposition that Minerva could not show that ADVANCED likely infringes a valid claim. Hologic raised a number of points, including that (a) ADVANCED's elements had not been "treated" for purposes of SDMP; (b) ADVANCED's elements had not undergone "different" treatments for purposes of SDMP; and (c) if ADVANCED's elements had undergone "different treatments" for purposes of SDMP, then CLASSIC's elements had also undergone "different treatments" and was prior art that invalidated Claim 13.

In reply to these points, Minerva broke the parties' agreement and unilaterally proffered a new construction of SDMP: "different thickness or width and different composition or treatment that provide different spring characteristics to influence the expandable planar triangular shape of the energy delivery surface." *Id.* at 14-15. On the basis of this changed construction, Minerva argued that while CLASSIC's inner and outer elements did not possess "different spring characteristics to influence the expandable planar triangular shape of the energy delivery surface," ADVANCED's inner and outer elements did. *Id.* at 3-5. These were unexpected positions that

unfairly disadvantaged Hologic, which had based its opposition on the agreed-upon construction of SDMP.

For the disposition of this motion, the Court declines to consider Minerva's revised construction. The Court's initial response at the hearing, when this problem fully surfaced, was to allow Hologic to file a sur-reply. Dkt. No. 78. But after further consideration of the record, the Court finds that that response gave Minerva too much credit for its conduct. This is because Minerva has failed to show a good reason for changing its construction. Minerva appears to suggest that it acquired new information after it started these motion proceedings, but that is not at all supported by the record. As Minerva acknowledges, the reply brief construction is based on evidence intrinsic to the '208 patent. Dkt. No. 66-4 at 2. And before Minerva filed the motion, it knew that its own expert, Dr. John Pearce, had stated his opinion that SDMP permits the frame to expand "to a more triangular shape that allows the energy delivery surface to make better contact with the endometrial wall of the uterine cavity. . . . [which] optimizes energy delivery to engaged tissue." Dkt. No. 35-29 at 6. None of this was unavailable when Minerva agreed to the original construction with Hologic, and none of it -- or anything else in the record -- justifies Minerva's subsequent abandonment of that construction.

That is enough to foreclose consideration of the reply brief construction, but it is also worth noting that Minerva's conduct breaches basic principles of claim construction. "[U]nless required by the specification, limitations that do not otherwise appear in the claims should not be imported into the claims." *N. Am. Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 1348 (Fed. Cir. 2005). Claim 13 does not contain the limitation that the inner and outer elements should possess "different spring characteristics to influence the expandable planar triangular shape of the energy delivery surface." *See* Dkt. No. 35-3 at 22:41-45. Nor is that limitation required by the specification, which only describes an embodiment wherein "a dielectric membrane can be expanded by a frame having frame elements with dissimilar spring characteristics . . . to optimize energy delivery to engaged tissue." *Id.* at 19:5-11. That example does not rise to the level of an intentional disclaimer or special definition applicable to the entire "SDMP" term. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005).

Consequently, Minerva will not be allowed to depart from the agreed-upon original construction for this motion. *See Keranos, LLC v. Silicon Storage Tech., Inc.*, 797 F.3d 1025, 1035 (Fed. Cir. 2015) (district courts may establish rules to "require parties to crystallize their theories of the case early in the litigation" and to "prevent the 'shifting sands' approach to claim construction"); *see also* Standing Order in Civil Cases at 4. The Court will review the arguments in Minerva's reply to the extent that they relate to the original construction.

A. "Treatments"

Hologic has raised substantial questions about infringement that undermine Minerva's ability to show a likelihood of success. One of these substantial questions involves the extent to which, if at all, ADVANCED's inner and outer elements undergo "treatments" for purposes of SDMP. In ADVANCED, both flexures are shaped through a photochemical etching procedure ("PEP"), which uses "a 'mask' (photoresist) that controls the exposure of a metal to an etchant." Dkt. No. 54 at 10-11. Different mask patterns are used to create the different features of each element. *Id.* PEP "removes material to form the metal's geometric shape" but does not change the metal's "inherent properties," such as alloy homogeneity, atomic crystal lattice structure, or grain structure. *Id.* at 9; *see also* Dkt. No. 66-9 at 15 (Minerva expert distinguishing "intrinsic material properties of a metal" from "component-level properties").

Minerva says that PEP is a "treatment" because the proverbial POSITA -- a person of ordinary skill in the art[1] -- would know that processes such as PEP can "change material properties by merely removing material from the surface of a physical thing." Dkt. No. 66-7 at 8. Minerva's primary evidence for this proposition is a 1998 handbook on surface engineering published by the American Society of Materials. *Id.* The handbook, however, emphasizes that the objective of surface engineering is to "allow the *surface* to perform functions that are distinct from those functions demanded from the bulk of the material." Dkt. No. 67-7 at ECF p. 5 (emphasis added); *see also id.* at ECF p. 8 (technique of electrochemical etching is "primarily used for obtaining

[1] According to Minerva, the POSITA here would be "someone with the equivalent of a bachelor's degree in biomedical engineering, electrical engineering, mechanical engineering, or a related field and at least two years of work experience developing or implementing electrosurgical devices." Dkt. No. 35-29 at 6-7. Hologic takes a similar position. Dkt. No. 54 at 5.

mirror-like surfaces"). At no point does Minerva explain how the objectives of surface engineering are accomplished by PEP as applied to ADVANCED's flexures. While Minerva suggests that a "critically" thinned region of the inner element allows ADVANCED to increase ablation coverage using a more compact device, Dkt. No. 35-29 at 21-23, those improvements have nothing to do with the distinctive surface properties of the inner element.

B. "Different"

Even if PEP as applied to ADVANCED is a "treatment," which the Court questions, Minerva can establish infringement only by showing that PEP applied to the inner flexure is a "different" treatment than PEP applied to the outer flexure. Common sense suggests that two pieces of metal treated by the same etching procedure undergo the same treatment, even if the result is two components with distinct shapes. Nevertheless, Minerva argues that the treatments are different for purposes of SDMP because "the inner frame elements have undergone a treatment that provides different spring characteristics than the outer elements to influence the expandable planar triangular shape of the energy delivery surface." Dkt. No. 66-4 at 4.

This rather tortured position suffers from several problems. To start, Minerva defines "different treatment" in a circular manner. Minerva has construed SDMP as "different thickness or width and different composition or treatment," and in essence proposes that treatments by the same procedure (PEP) are different so long as they result in different material properties. In addition, it is not at all clear that a POSITA would understand the term "material properties" to include spring characteristics. As Minerva acknowledges, spring characteristics are "component-level" properties that depend not only on the material's intrinsic properties but also on the geometry of the component. Dkt. No. 66-9 at 15. Minerva's experts contend that such component-level properties are considered material properties, *see, e.g.*, Dkt. No. 66-7 at 3, while Hologic's expert argues the exact opposite, Dkt. No. 54 at 10. The parties have presented directly conflicting expert declarations, and the intrinsic evidence does not resolve that dispute. The '208 patent specification only describes embodiments where the inner and outer components possess different spring characteristics by virtue of being constructed from dissimilar materials. Dkt. No. 35-3 at 19:48. But the converse does not follow -- those examples do not show that two

components have "substantially different material properties" whenever they have different spring characteristics. As a whole, the record does not support a finding that "material properties" includes spring characteristics.

Even were the Court to accept Minerva's definition of "different treatment," it has failed to present evidence of infringement. Under Minerva's view of Claim 13, ADVANCED infringes if the inner and outer elements have different spring characteristics influencing the shape of the energy delivery surface. But Minerva's reply brief never compares the spring characteristics of ADVANCED's inner and outer elements. *See* Dkt. No. 66-4 at 4. Instead, Minerva simply emphasizes that the narrowed "critical" region of ADVANCED's inner flexure "altered spring characteristics of the inner element by as much as 130% as compared to the same element without such thin region." *Id.* The relevance of this observation is not explained, and it is far from clear why Minerva's theory of infringement is advanced by comparing the spring characteristics of the actual inner element with those of a completely hypothetical inner element.

While the record has some data on the spring characteristics of ADVANCED's and CLASSIC's inner and outer elements, Minerva never discussed it in the reply brief, and so it is of little consequence. It is enough to note that Minerva's expert measured the bending stiffness of ADVANCED's inner element to be 0.724 psi-in and the bending stiffness of the outer element to be 0.186 psi-in. Dkt. No. 66-9 at 19-21. Minerva makes no attempt to explain to what extent this difference in bending stiffness should be attributed to difference in thickness or width, to what extent it should be attributed to "different treatment," or to what extent it makes any material difference to the injunction request.

As a result, the Court has no basis for finding that the PEP processes applied to the inner and outer elements contributed to a difference in spring characteristics. In addition, a common-sense reading of the data would appear to undermine Minerva's argument. That is because the bending stiffness of a hypothetical thicker inner flexure was measured to be 1.68 psi-in, while the bending stiffness of the actual inner flexure was 0.724 psi-in. *Id.* at 19. Minerva's data, in other words, seems to support the view that PEP actually decreased the delta in bending stiffness between the inner and outer flexures.

Consequently, the record raises serious questions about the merits of Minerva's infringement claim. Hologic also challenged the validity of Claim 13, but the Court need not take up those arguments because the infringement question resolves the motion. This is not to say that Minerva's claim is a completely lost cause, only that Minerva has not shown a likelihood of success warranting an injunction.

II. Irreparable Harm And Balance Of Equities

In the absence of a likelihood of success on the merits, Minerva cannot win an injunction. A full stop at this point is warranted, but for the sake of completeness, the Court also finds Minerva has not shown a threat of irreparable harm. Minerva says that it has suffered lost business opportunities, and erosion of exclusivity, goodwill, reputation, and product prices. In support of these claims, Minerva relies largely on cursory single-page declarations from its sales representatives. Minerva has not submitted any declarations from physicians or customers, any relevant sales figures, or any expert analysis of sales or the market.

On erosion of exclusivity, goodwill and reputation, Minerva argues that customers "no longer distinguish Minerva from Hologic as a provider of endometrial ablation devices that are less painful than previous generation technologies." Dkt. No. 34-4 at 12. In opposition, Hologic points out that Minerva has presented no evidence that Minerva EAS had an exclusive reputation as a less painful product. Dkt. No. 51-4 at 12. Minerva effectively concedes the point by failing to address it in the reply brief with anything more than a footnote citation to anecdotal testimony by its own CEO. *See* Dkt. No. 66-4 at 9 n. 8.

On price erosion, Minerva says it is being forced to offer Minerva EAS at a lower price due to Hologic's pricing strategies for ADVANCED. Dkt. No. 34-4 at 12-13. Minerva's sole evidence of price erosion is a declaration by Mary Hanley, a Minerva sales representative. *See* Dkt. No. 34-14. Hanley states that "one physician who had previously agreed to use the Minerva EAS for in-office endometrial ablation procedures" informed her that he would able to purchase ADVANCED for $695. Minerva offered to drop its price from over $1000 to $850, but the physician declined the offer. This lone example is far too slender a reed to support a finding that Minerva is suffering appreciable price erosion from the availability of ADVANCED.

Minerva fares no better on proof of lost sales or business opportunities. As an initial matter, Minerva's evidence that it has lost sales or is likely to is again close to threadbare. At most, it identifies a handful of accounts that gave up Minerva's product for ADVANCED. *See, e.g., id.* Minerva also points out that some physicians have switched from using EAS to using ADVANCED. *See* Dkt. No. 34-8 (Capone declaration) (a physician who used EAS intends to try ADVANCED and views it as an "upgrade"); Dkt. No. 34-12 (Fratantoro declaration) (some physicians have switched from EAS to ADVANCED). But Minerva acknowledges that those examples are of individual physicians who perform ablation procedures through medical facilities that have continued to purchase Minerva EAS since the launch of ADVANCED. *See* Dkt. No. 66-5 at 2. There is no indication in the record that those medical facilities have reduced their orders of Minerva EAS.

Even were the Court to look past Minerva's scant evidence of lost sales, Minerva has not established a causal nexus between any lost sales and the alleged infringement. *Genband*, 861 F.3d at 1384. Assuming for discussion purposes only that ADVANCED can offer a narrower sheath than CLASSIC and EAS because it embodies the '208 patent, Minerva acknowledges that ADVANCED has been marketed as an improvement over CLASSIC not only for its narrower sheath, but also for a larger cervical seal collar and rounded, smooth access tips. Dkt. No. 34-9 at 7. And in some treatment contexts, such as hospitals, where the patient is typically anesthetized during the ablation procedure, customers may put less value on ADVANCED's narrower sheath. Dkt. No. 51-23 at 196, 163. For these reasons, to the extent that Minerva has identified lost sales, it fails to show that those sales were substantially influenced by ADVANCED's narrower sheath diameter.

To be sure, the evidence indicates that some physicians have thought about buying ADVANCED. But that is hardly a substantial sign that potential infringement is driving lost sales. It is objectively reasonable to expect that treatment providers will consider all available options when deciding which surgical instruments to buy, and ADVANCED's presence in that mix or in the market is not in itself proof of sales lost to Hologic due to infringement. Minerva has identified only one account that was committed to purchasing Minerva EAS but instead purchased

ADVANCED. *See* Dkt. No. 34-14 (Hanley declaration). Even so, Minerva presents no specific facts suggesting that that account chose ADVANCED because of its narrower sheath, rather than because of ADVANCED's lower price or for other reasons. Indeed, Minerva proffered a physician's testimony that diameter was not a reason he preferred Hologic devices over Minerva devices. *See* Dkt. No. 66-11 at 33-34 ("There is a difference between the NovaSure Classic and the Minerva, but the diameter is actually not a consideration for me in terms of use of either product. It's really the technology difference because for 12, 14 years I've used the Classic without an issue in my office. If a smaller one is available, fine, I'll use it, but, otherwise, I'll go back to Classic."). On the whole, Minerva has failed to present evidence "that soundly supports an inference of causation of a significant number of purchasers' decisions." *Genband*, 861 F.3d at 1384.

Minerva's other allegations of injury are largely unsubstantiated. For example, Minerva claims that "Hologic is selling ADVANCED to more than 80 customers . . . that Minerva had suspected to losing to ADVANCED." Dkt. No. 66-4 at 8-9. Minerva offers no evidence of any causal nexus to infringement beyond that expression of its own suspicions. Minerva does not even specify which of those accounts were previous customers of either Minerva or Hologic. *See* Dkt. No. 66-20.

Overall, Minerva's presentations on lost sales and business opportunities are too spare and unsupported to find irreparable harm. Minerva's delay in filing this motion also undercuts a showing of irreparable harm. Before this case was filed, Minerva and Hologic were already involved in litigating patent disputes over their endometrial ablation devices. *See Hologic, Inc., et al. v. Minerva Surgical, Inc.*, No. 15-1031-SLR, 2016 WL 3143824, at *1 (D. Del. June 2, 2016). As a general matter, parties engaged in patent litigation typically watch each other like hawks for evidence of potential infringement. For the devices at issue here, Minerva was aware by November 2016 of the impending U.S. launch of ADVANCED. *See, e.g.*, Dkt. No. 51-23 at 118-124. At that time, Minerva sales representatives were already reporting to management that Hologic had told customers not to commit to Minerva EAS because ADVANCED would soon be available. *Id.*

Consequently, as of the end of 2016, Minerva was on reasonable notice that Hologic was in the process of releasing a new endometrial ablation device that would challenge Minerva EAS. Nevertheless, it did not file this suit until April 2017, Dkt. No. 1, or seek an injunction until August 2017, Dkt. No. 32. At the preliminary injunction hearing, Minerva's explanation for this drawn-out timeline is that it had trouble obtaining an ADVANCED device before March 2017 and that Minerva undertook extensive analysis of infringement and irreparable harm before filing its complaint and subsequent injunction motion. Dkt. No. 79 at 28-30. But Minerva has not presented to the Court evidence of problems in getting the devices. *See, e.g.*, Dkt. No. 66-4 at 9 (discussing timing solely in terms of time spent investigating infringement). In the absence of a factual record that can justify a nine month delay between notice and filing of a preliminary injunction motion, the Court finds that the delay undermines Minerva's showing of irreparable harm. *See Apple*, 678 F.3d at 1325.

In light of these conclusions, and the lack of a showing of a likelihood of success on the merits, the answer to whether the balance of equities tips in Minerva's favor is straightforward. It does not.

III. Public Interest

As a final note, the Court has serious doubts that the public interest weighs in favor granting a preliminary injunction. Minerva says that a preliminary injunction would protect the public's interest in enforcing patent rights while not resulting in a shortage of endometrial ablation devices. Dkt. No. 34-4 at 15. Vindication of valid patent rights is without a doubt in the public's interest, but that factor is less germane here in light of Minerva's failure to demonstrate a likelihood of success on the merits.

Of greater concern is the evidence in the record indicating that enjoining ADVANCED would limit women's treatment options in ablation procedures. Minerva's CEO describes ADVANCED as embodying "a very well thought out and well-designed change," resulting in a narrower 6 millimeter sheath that produces "a real advantage" for the patient. Dkt. No. 51-23 at 387, 238 ("from a 6 to an 8, when you're a patient that is under minimal anesthesia, and somebody is stretching and potentially tearing the muscles of your cervix, it's not something that goes

unnoticed"). This is particularly true in an office treatment setting, where patients prefer to be cared for, in possible contrast to hospitals and their use of full anesthesia. *See* Dkt. No. 66-4 at 8; Dkt. No. 51-23 at 162. Although other devices with comparably narrow sheaths are available on the market, Minerva's CEO acknowledges that they are not as effective as ADVANCED. *Id.* at 328-29.

These facts give substantial support to the proposition that ADVANCED offers ablation patients a greater degree of effectiveness and comfort than other options on the market, specifically in the office setting. Consequently, the public interest is unlikely to be served by an injunction. *See, e.g.*, *Cordis Corp. v. Boston Sci. Corp.*, 99 F. App'x 928, 935 (Fed. Cir. 2004).

CONCLUSION

The motion for a preliminary injunction is denied.

IT IS SO ORDERED.

Dated: January 5, 2018

JAMES DONATO
United States District Judge

United States District Court
Northern District of California